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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/532,209	04/22/2005	Samuel Sowemimo-Coker	441071/PALL	6768
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EXAMINER				
CHRISTIAN, MARJORIE ELLEN				
ART UNIT		PAPER NUMBER		
1797				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/532,209

**Applicant(s)**

SOWEMIMO-COKER ET AL.

**Examiner**

MARJORIE CHRISTIAN

**Art Unit**

1797

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 April 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date 1/13/2009, 6/1/2005, 4/22/2005
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Summary*

1. This is the initial Office action based on the application filed April 22<sup>nd</sup>, 2005.
2. Claims 1-21 are pending and have been fully considered.

### *Information Disclosure Statement*

3. The information disclosure statement filed 1/13/2009 fails to comply with 37 CFR 1.98(a)(2), which requires a **legible copy of each cited foreign patent document**; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information lined through has not been considered. All other information has been considered.

The information disclosure statement filed 1/9/2005 fails to comply with 37 CFR 1.98(a)(3) because it does not include **a concise explanation of the relevance**, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information lined through has not been considered. All other information has been considered.

### *Claim Rejections - 35 USC § 112*

4. Claims 1-11, 19-21 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential structural cooperative relationships of elements,

such omission amounting to a gap between the necessary structural connections. See MPEP § 2172.01. The omitted structural cooperative relationships are: how the first and second leukocyte depletion filters elements and plurality of layers are linked. For purposes of interpretation it is assumed that the filter elements are linked in series and are in communication with each other.

***Claim Rejections - 35 USC § 102/103***

5. **Claims 1-3, 5, 7-8, 16-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over US Patent No. 4,701,267, WATANABE et al. (hereinafter WATANABE).**

As to Claims 1-3, 5, 7-8, WATANABE discloses a biological fluid filter (Abstract) comprising: first porous leukocyte depletion filter element and second porous leukocyte depletion filter element (Fig. 4, Ref. 6, 10) comprising: a plurality of layers of fibrous media (Fig. 4, Ref. 6, 10); first filter element having a different basis weight than the second filter element (Examples 1-6). WATANABE does not appear to expressly disclose the basis weight of the filter elements and P8 value of the filter elements. However, it is inherent based on the bulk density, density, average diameter of fibers and thickness and diameter of disks that each porous leukocyte depletion filter element has a basis weight of about 15 to about 30 g/ft<sup>2</sup> (Examples 1-6) and that the first filter element has a P8 value of about 15 to about 18 inches of water, and the second filter element has a P8 value of about 13.5 inches of water or less, absent evidence to the contrary.

As to Claims 16-17, WATANABE discloses a method for processing a biological fluid comprising: passing a leukocyte-containing biological fluid through the filter of claim 1 (see 102(b) rejection of Claim 1) to provide a leukocyte-depleted biological fluid (Examples 1-3) that contains less than  $5 \times 10^6$  residual leukocytes per unit of biological fluid (Example 2).

6. **Claims 5-6, 12-15, 21 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over WO2000/54873, BORMANN et al. (hereinafter BORMANN).**

As to Claims 5, BORMANN discloses at least one porous leukocyte depletion filter comprising a plurality of layers of fibrous media (Fig. 1). BORMANN does not appear to expressly disclose the P8 value of the filter element. However, it is inherent that the element has a P8 of at least about 14.5 inches of water, absent evidence to the contrary.

As to Claim 6, BORMANN discloses the leukocyte depletion filter element has a pore diameter in the range of from about 2  $\mu\text{m}$  to 6  $\mu\text{m}$ . (Pg. 15, Line 30- Pg. 16, Line 3, Example 4).

As to Claims 12-13, BORMANN discloses a method for processing biological fluid comprising: passing a leukocyte-containing biological fluid through a biological fluid filter (Fig. 4) including at least one porous leukocyte depletion filter element comprising a plurality of layers of fibrous media, to deplete leukocytes from the biological fluid

(Example 1), where it is inherent that the element has a P8 of at least about 15 inches of water, absent evidence to the contrary.

As to Claim 14, BORMANN discloses the leukocyte-containing biological fluid is filtered within about 24 hours of collection (Example 2).

As to Claim 15, BORMANN discloses the biological fluid is filtered while maintaining a closed system (Example 1, Fig. 4).

As to Claim 21, BORMANN discloses each of the plurality of layers of fibrous media (Fig. 1, Ref , 1, 2) has an upstream surface (30) and a downstream surface (20), and the filter includes adjacent layers having contacting surfaces wherein the surfaces are not thermally or adhesively bound to each other (Example 1, Fig. 1).

### ***Claim Rejections - 35 USC § 103***

7. **Claims 4, 9, 10-11, 19-20 are rejected under 35 USC 103 (a) as being obvious over US Patent No. 4,701,267, WATANABE et al. (hereinafter WATANABE) in view of WO2000/54873, BORMANN et al. (hereinafter BORMANN).**

As to Claims 4, 9, 11, 19, WATANABE discloses the porous filter elements with each porous leukocyte depletion filter element having a basis weight of about 15 to about 30 g/ft<sup>2</sup> (as shown in the 102/103 rejection of claims 1, 2, 5, 7-8, 10). WATANABE does not appear to expressly disclose the critical wetting surface tension. However, BORMANN discloses the first and second leukocyte depletion filter elements have a critical wetting surface tension of at least about 85 dynes/cm (Pg. 12, Lines 2-9).

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the porous filter elements of WATANABE to include the critical wetting surface tension of BORMANN. The motivation would have been to have filter elements that deplete and prevent activation of complement in biological fluids (Pg. 2, Lines 16-23). Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

As to Claims 10, 20, BORMANN discloses each of the plurality of layers of fibrous media (Fig. 1, Ref , 1, 2) has an upstream surface (30) and a downstream surface (20), and the filter includes adjacent layers having contacting surfaces wherein the surfaces are not thermally or adhesively bound to each other (Example 1, Fig. 1).

### ***Conclusion***

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to MARJORIE CHRISTIAN whose telephone number is (571)270-5544. The examiner can normally be reached on Monday through Thursday 7-5pm (Fridays off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, David R. Sample can be reached on (571)272-1376. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MC

/Krishnan S Menon/  
Primary Examiner, Art Unit 1797